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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/134,771	08/12/98	SAH	D 860098.425
		HM12/1213	EXAMINER MAYO, K
			ART UNIT 1623
			PAPER NUMBER 5
		DATE MAILED: 12/13/99	

Please find below and/or attached an Office communication concerning this application or proceeding.

**Commissioner of Patents and Trademarks**

## Office Action Summary

Application No. 09/134,771	Applicant(s) Sah et al.
Examiner Kris Pelham Mayo	Group Art Unit 1633



Responsive to communication(s) filed on \_\_\_\_\_.

This action is FINAL.

Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 1 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

### Disposition of Claims

Claim(s) 1-24 is/are pending in the application.

Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

Claim(s) \_\_\_\_\_ is/are allowed.

Claim(s) \_\_\_\_\_ is/are rejected.

Claim(s) \_\_\_\_\_ is/are objected to.

Claims 1-24 are subject to restriction or election requirement.

### Application Papers

See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

The proposed drawing correction, filed on \_\_\_\_\_ is  approved  disapproved.

The specification is objected to by the Examiner.

The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. § 119

Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

All  Some\*  None of the CERTIFIED copies of the priority documents have been received.

received in Application No. (Series Code/Serial Number) \_\_\_\_\_.

received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_.

Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

### Attachment(s)

Notice of References Cited, PTO-892

Information Disclosure Statement(s), PTO-1449, Paper No(s). \_\_\_\_\_

Interview Summary, PTO-413

Notice of Draftsperson's Patent Drawing Review, PTO-948

Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

## **DETAILED ACTION**

### ***Election/Restriction***

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-15, 23 and 24 drawn to a method for producing a conditionally-immortalized human mesencephalon neural precursor cell, a conditionally-immortalized human mesencephalon neural precursor cell and clonal cell line, a method of using a conditionally immortalized human mesencephalon neural precursor cell to produce neurons, and a neuron produced by the method of using a conditionally immortalized human neural precursor cell to produce neurons classified in class 435, subclass 1.1, class 435, subclass 368, class 435, subclass 325, and class 435, subclass 368 for example.
- II. Claims 16 and 17, drawn to a method of transplanting a human mesencephalon precursor cell or neuron, and a method of treating Parkinson's disease with a human mesencephalon precursor cell or neuron, classified in class 424, subclass 93.7, for example.
- III. Claims 18 and 21, drawn to an in vitro assay for an agent that modulates activity of a protein produced by a human mesencephalon cell, and a method for screening for an agent that affects human mesencephalon cell death, classified in class 435, subclass 4, for example.

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- IV. Claim 19, drawn to an in vitro assay to test for the presence of protein in a sample, such as by antigen-antibody binding, classified in class 435, subclass 7.1, for example.
- V. Claim 20, drawn to a method for identifying a human mesencephalon gene or protein, such as by PCR or hybridization techniques, classified in class 435, subclass 6, for example.
- VI. Claim 22, drawn to a method for screening for a cellular protein that regulates human mesencephalon cell death, classified in class 435, subclass 4, for example.

The inventions are distinct, each from the other because of the following reasons:

Inventions I-VI are drawn to non-equivalent, patentably distinct methods. A method of producing a conditionally immortalized human mesencephalon neural precursor cell, and then using said neural precursor cell to produce neurons would involve different process steps, functions, and technical strategies than a method of transplanting a human mesencephalon precursor cell or neuron into a recipient, and a method of treating Parkinson's disease with said precursor cell or neuron. Additionally, methods of in vitro antigen-antibody binding assay to test for the presence of protein in a sample would involve different technical steps and strategies from methods of in vitro PCR and hybridization assay to identify the presence of a gene or protein. Similarly, methods for screening for agents that modulate and affect human mesencephalon cell death would involve different method steps, reagents and technical strategies than methods of

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transplantation, Parkinson's disease treatment, antigen-antibody binding assays, PCR's and hybridization assays. Furthermore, a method of screening for a cellular protein that regulates human mesencephalon cell death would involve different process steps and functions than any of the other claimed methods. Finally, the distinctions are further underscored by their different classification; the different inventions would require divergent searches, as the search for one would not be expected to reveal all the references relevant to the other. The search and examination, therefore, would be unduly burdensome.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Applicant is advised that the response to this requirement must include an election of the invention to be examined, even though the requirement be traversed. (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(h).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kris Pelham Mayo, whose telephone number is (703)306-5877. The

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examiner can normally be reached on Monday-Thursday, and alternating Fridays from 8:00 a.m. to 5:00 p.m. (Eastern Time).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jasemine Chambers, can be reached at (703)308-2035. The FAX telephone number for group 1600 is (703)308-4242.

An inquiry of a general nature or relating to the status of the application should be directed to the group receptionist whose telephone number is (703)308-0196.



DEBORAH J. CLARK  
PATENT EXAMINER

Kris Pelham Mayo, D.V.M.  
Patent Examiner  
Art Unit 1633  
December 9, 1999